



Arnold B. Calmann
(973) 645-4828
abc@saiber.com

July 22, 2022

BY CM/ECF

The Honorable Evelyn Padin, U.S.D.J.
United States District Court for the District of New Jersey
Frank R. Lautenberg P.O. Building and U.S. Courthouse
One Federal Square
Newark, NJ 07102

**Re: *Metacel Pharmaceuticals, LLC v. Rubicon Research Private Limited*
Civil Action No. 21-19463-EP-JRA**

Dear Judge Padin:

We, along with our co-counsel, Arnall Golden Gregory LLP, represent Plaintiff Metacel Pharmaceuticals LLC ("Metacel") in the above-captioned matter. Pursuant to the Court's April 8, 2022 Order (ECF No. 35), Metacel and Defendant Rubicon Research Private Limited ("Rubicon") jointly submit this status letter, which includes (1) a summary of the relevant facts and the parties' legal positions; (2) the status of the case; (3) a summary of pending motions; (4) a summary of settlement discussions; and (5) a summary of pending issues.

I. Background and Legal Positions

This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271 specifically, filed by Metacel in response to Rubicon's filing of Abbreviated New Drug Application ("ANDA") No. 214445 with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Metacel's branded Ozobax® baclofen oral solution 5mg/5mL. Rubicon seeks approval to commercially market a generic version of Ozobax® prior to the expiration of United States Patent No. 10,610,502 (the "'502 Patent" or "Patent-in-suit") owned by Metacel. Generally, the Patent-in-suit claims, *inter alia*, a method for relaxing muscles or treating spasticity by administering a baclofen oral solution and certain additional steps regarding testing and storage of the solution.

Rubicon has asserted the following affirmative defenses: (1) that Rubicon does not and will not infringe any valid and enforceable claim of the '502 Patent; (2) that the claims of the '502 Patent are invalid and/or unenforceable under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112; (3) that Metacel is estopped from maintaining that any valid or enforceable claim of the '502 Patent is infringed by the product that is the subject of Rubicon's ANDA No. 21445; and (4) that Metacel fails to state a claim upon which relief may be granted. At this stage, the legal issues in this case concern whether Rubicon's marketing of its ANDA product, if approved, will infringe any valid claims of the Patent-in-suit. Rubicon contends that its non-infringement position can and should be decided on early summary judgment.

Honorable Evelyn Padin, U.S.D.J.

July 22, 2022

Page 2

II. Status of the Case

At this time, the parties have undertaken discovery efforts in the form of written discovery, document production, and production of samples of finished ANDA product. The parties have served contentions and responses on both infringement and invalidity pursuant to the Local Patent Rules.

Document production and fact discovery is underway and the parties intend to proceed with document production and claim construction according to the Scheduling Order. The parties are meeting and conferring regarding Metacel's request for production of samples of raw materials and intermediate product, but this issue is not yet ripe for Court consideration. As part of the parties' meet and confer process regarding Metacel's ongoing request for production of samples of raw materials and intermediate product, Metacel has repeatedly advised Rubicon that receipt and use of the requested samples may lead to additional claims of infringement and the need to seek leave of the Court to amend its current infringement contentions to (i) supplement Metacel's current infringement contentions based on the doctrine of equivalents and/or (ii) supplement Metacel's current infringement contentions to add a claim for direct infringement. Metacel is attempting to complete the meet and confer process expeditiously to avoid any delay in this case. Rubicon opposes the request for raw materials and intermediate products as the requests were overly broad and an impermissible fishing expedition designed to delay the case. Rubicon has stated that as presently advised it would oppose any motion filed by Metacel to seek leave to supplement or otherwise amend its infringement contentions based on the outcome of Metacel's request for samples of raw materials or intermediate product.

Metacel has identified a single claim term that may need a specific construction, and as presently advised, does not propose any other term for claim construction. However, as Metacel advised the Court during the initial scheduling conference, full briefing and the Court's ruling on claim construction is necessary before the parties engage in requests to file any dispositive motions. Rubicon notes that the Court disagreed with Metacel's position as reflected in Paragraph 35 of the Scheduling Order permitting Rubicon to move for leave to file a motion for summary judgment of non-infringement at this time. Rubicon did not propose any term for claim construction and does not believe the term identified by Metacel needs any construction, opposes Metacel's proposed construction and has offered its own in accordance with local rule. Claim construction proceedings are following the Scheduling Order and the local rules of this Court.

III. Settlement Discussions

The parties have been actively engaged in settlement discussion, but have not yet reached a resolution. Metacel proposes that a Court-ordered, one day mediation within the next 45-60 days to resolve any remaining issues would benefit the parties' settlement efforts, which if successful, would also conserve judicial resources. Metacel's counsel would propose a brief telephone conference if further clarification would be helpful to the Court. Rubicon is in favor of mediation if needed, but believes it is premature given the specific status of negotiations. Rubicon would be

Honorable Evelyn Padin, U.S.D.J.

July 22, 2022

Page 3

willing to engage in mediation at a later date if the parties are not able to reach a resolution on their own.

IV. Pending Motions

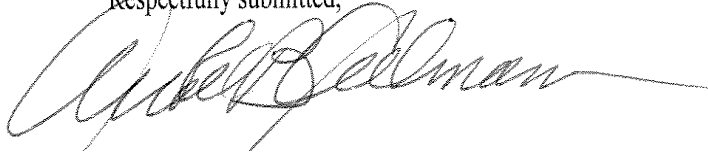
At this time, there are no motions pending in this case.

V. Pending Issues

There are no pending matters before the Court at this time, but the following events are expected in the near future: (1) the parties will attend a status conference with Magistrate Judge Almonte on July 25, 2022; (2) the parties will file their Joint Claim Construction and Prehearing Statement on or before August 17, 2022, as required by Paragraph 14 of the Scheduling Order; (3) if the parties are unable to resolve Rubicon's present objections to producing raw material and intermediate product samples, Metacel will raise this issue with the Court; and (4) Rubicon anticipates seeking leave to file a motion for summary judgment on non-infringement as permitted by Paragraph 35 of the Scheduling Order.

We thank the Court for its consideration and continued assistance in this matter.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Arnold B. Calmann", with a long horizontal flourish extending to the right.

Arnold B. Calmann

cc: Counsel of record (by CM/ECF)